SEP 1 8 2000



K002322

KURARAY CO., LTD.
12-39, 1-Chome, Umeda, Kita-ku, Osaka 530-8611, JAPAN
Phone : +81-6-348-2603
Facsimile: +81-6-348-2552

# 510(k) SUMMARY

1. Submitter

| | |
|---|---|
| 1) Name | KURARAY CO., LTD. |
| 2) Address | 1-12-39, Umeda, Kita-ku, Osaka 530-8611, Japan |
| 3) Telephone | 81(Japan)-6-348-2603 |
| 4) Facsimile | 81(Japan)-6-348-2552 |
| 5) Contact person | Shinichi Sato<br>Dental Material Department<br>Medical Products Division |
| 6) Date | June 27, 2000 |

2. Representing (Subsidiary of KURARAY CO., LTD.)

| | |
|---|---|
| 1) Name | KURARAY AMERICA INC. |
| 2) Address | 30th Fl. Metlife Building, 200 Park Avenue, New York, NY 10166 |
| 3) Telephone | (212)-986-2230 |
| 4) Facsimile | (212)-867-3543 |
| 5) Contact person | Koichi Kikuchi<br>President |

3. Name of Device

| | |
|---|---|
| 1) Proprietary Name | PANAVIA F |
| 2) Classification Name | Dental Cement (21 CFR 872.3275) |
| 3) Common/Usual Name | Dental Adhesive |

4. Predicate devices:

| | | |
|---|---|---|
| 1. | PANAVIA F by Kuraray Co., Ltd. | (K983361) |
| 2. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |
| 3. | 3M LVR SYSTEM by 3M Co. | (K991961) |
| 4. | VARIOLINK II by Ivoclar North America Inc. | (K971372) |
| 5. | C&B META BOND by Perkell | (K960464) |

5. Description for the premarket notification

PANAVIA F is classified into dental cement, CFR 21 Section 872.3275, because it is a device composed of materials such as dimethacrylate monomers and inorganic fillers intended to be used for cementation of dental devices such as crowns or bridges.

This product is similar and substantially equivalent in design, composition and function to dental cements which are identified in the paragraph 4 of this summary; all of which are safe,

effective and beneficial.

6. Statement of the intended use

This device is used for cementation of dental devices such as crowns or bridges. One indication for cementation of porcelain veneers is added to the original indication of PANAVIA F (K983361). The indication is same to that of dental cements as shown below.

1) Cementation of metal crowns and bridges, inlays and onlays

| | | |
|---|---|---|
| 1. | PANAVIA F by Kuraray Co., Ltd. | (K983361) |
| 2. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |
| 3. | C&B META BOND by Perkell | (K960464) |

2) Cementation of porcelain crowns, inlays, onlays and veneers.

| | | |
|---|---|---|
| 1. | PANAVIA F by Kuraray Co., Ltd.America, Inc. | (K983361) |
| 2. | 3M LVR SYSTEM by 3M Co. | (K991961) |
| 3. | VARIOLINK II by Ivoclar North America Inc. | (K971372) |

[Remark]

The indication of PANAVIA F (K983361) is cementation of porcelain crowns, inlays and onlays.

3) Cementation of composite resin crowns, inlays and onlays

| | | |
|---|---|---|
| 1. | PANAVIA F by Kuraray Co., Ltd. | (K983361) |
| 2. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |
| 3. | VARIOLINK II by Ivoclar North America Inc. | (K971372) |

4) Cementation of adhesion bridges and splints

| | | |
|---|---|---|
| 1. | PANAVIA F by Kuraray Co., Ltd. | (K983361) |
| 2. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |
| 3. | C&B META BOND by Perkell | (K960464) |

5) Cementation of metal cores and prefabrication posts

| | | |
|---|---|---|
| 1. | PANAVIA F by Kuraray Co., Ltd. | (K983361) |
| 2. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |

6) Bonded amalgam restorations

| | | |
|---|---|---|
| 1. | PANAVIA F by Kuraray Co., Ltd. | (K983361) |
| 2. | PANAVIA 21 by Kuraray Co., Ltd. | (K933030) |

7. Statement of the technological characteristics and safety

This device is an improved product of PANAVIA F (K983361) and modified in its chemical compositions of components. These modifications do not affect the safety and effectiveness.

7-1 Technological characteristics

This device is a resin based cement cured chemically and by visible light activation. This device consists of Paste (A and B pastes), ED Primer (Liquids A and B), ALLOY PRIMER, Oxyguard II, and accessories as same as PANAVIA F (K983361).

The indication of this device is same as those of the similar devices sold in U.S. market. (The detail information is described in the paragraph 6 of this summary.) Therefore, this device is substantially equivalent in intended use and performance to that of products sold in the U.S. market.

7-2 Chemical ingredients and safety

The chemical compositions of the paste are changed from those of PANAVIA F (K983361) and other components are same to those of PANAVIA F. Because all chemical ingredients have been used in PANAVIA F, the safety of this device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Mr. Koichi Kikuchi
President
Kuraray America, Incorporated
Subsidiary of Kuraray Company Limited, OSAKA
200 Park Avenue
New York, New York 10166-3098

Re: K002322
Trade Name: Panavia F
Regulatory Class: II
Product Code: EMA
Dated: July 24, 2000
Received: July 31, 2000

Dear Mr. Kikuchi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K002322

DEVICE NAME: PANAVIA F

INDICATIONS FOR USE:

PANAVIA F is indicated for the following applications:

1) Cementation of metal crowns and bridges, inlays and onlays.
2) Cementation of porcelain crowns, inlays, onlays and veneers.
3) Cementation of to composite resin crowns, inlays and onlays
4) Cementation of adhesion bridges and splints
5) Cementation of metal cores and prefabrication posts
6) Bonded amalgam restorations

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002322